



ORTHO MEDICO

C L I N I C A L T R I A L

ORTHOMEDICO Inc.

Participant Recruitment and Market Research





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Company Introduction



Company Profile

Company Name ORTHOMEDICO Inc.

Establishment 2005/06

Capital Stock 75M yen

President Kazuo Yamamoto

Staff members Full-time: 50
Part-time: 75

Address 〒112-0002
2F Sumitomo Fudosan Korakuen Bldg., 1-4-1 Koishikawa, Bunkyo-ku,
Tokyo, Japan

Website <https://www.orthomedico.jp/english.html>

Area of business

1. Clinical Trial
2. Agent for submission of notifications
3. Participant recruitment
4. Market Research
5. Research Study Group Organization
6. Outcome Development
7. Overseas Business



山本和雄
Kazuo Yamamoto
President/ CEO



External Advisors

Medical Advisor



Tsuyoshi Takara

Academic consultant (Medicine)
Major Contributor of our clinical trials
Director of Takara Clinic



Sunao Kubota

Academic consultant (Medicine)
Head of IRB
Former Prof. at St. Marianna University
School of Medicine

Yoshihisa Abo (Director of D.Clinic)

Tatsuya Izumi (Director of Hiroo Skin Clinic)

Dentistry Advisor

Koichi Matsuo

(Chairperson of Koyukai, Medical Corporation)

Takuya Hamajima

(Chairperson of Shinseikai, Medical Corporation)

Legal Advisor

Keiichiro Ando

(Deputy Representative, Suda Law Office)

Certified Public Accountant

Kenichiro Nakamura

(Representative of ASC Inc. Nakamura Accounting Firm)

We constantly seek advice from external advisors to ensure the quality of our service.



A Brief History of ORTHOMEDICO

- 人 In 06/2005, ORTHOMEDICO was created as a subdivision in Tokyo Medical and Dental University.
 - Sole purpose was to **evaluate food safety**
- 人 Over the years, ORTHOMEDICO has evolved enormously from a small division in a university to a **major company** with numerous clients both locally and internationally.

**Our passion for ensuring food safety has remained unchanged.
Sparing no effort in proving the safety of our clients' food products!**



Clinical Trial

As a food product CRO, we support clinical trials while evaluating safety and efficacy information as a third-party organization.

If this is your first time gathering evidence for your product, we can also provide you support for basic research (preclinical research).



Agent for Submission of Notifications (to Gov't authority)

We provide dossier preparation assistance for clients to submit notifications of their products to the health authority as Foods with Function Claims. 2 methods are available:

- ✓ Result of a clinical trial
- ✓ Systematic review

As we, ORTHOMEDICO Inc., have experience in both methods, anyone regardless of their experience in the field can rest assured and leave it all to us.



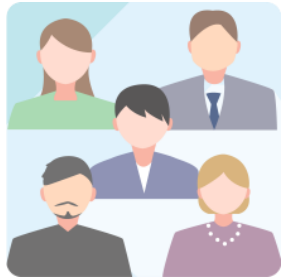
Research Study Group Organization

We offer support to activities that aim to deepen and broaden one's knowledge based on medicine and nutritional science. Specifically, we do so by holding study groups and research seminars, and building bridges between businesses and clinical medical practitioners and those between businesses and academia.



Market Research Assistant

By organizing these surveys and opinion sharing sessions, customers are allowed to voice their opinions freely. With the first-hand opinions obtained through these sessions, the development and marketing of your products can be further enhanced



Participant Recruitment

In ORTHOMEDICO Inc., a specially designed website known as Go106.jp is used to recruit participants for clinical studies. As health checks are provided to registered individuals regularly, we are able to constantly find the most suitable group of candidates for each individual clinical studies.



Outcome Development

We help clients develop and study clinical outcomes parameters that can be used in healthy individuals, as compared to those preexisting outcomes that are commonly disease based and patient-targeted.



Overseas Enterprise



Support to overseas enterprise

- Acquisition of scientific evidence of Asian population
- Agent for notification as food with functional claims
- Organization of study groups and seminars to promote clients' products /idea.
- Expansion of business to the Japanese market

Japanese Enterprise



Support to local enterprise

- Acquisition of scientific evidence of overseas non-Asian population
- Expansion of business to overseas market






Participant Recruitment

Suboptimal health

-  As a pioneer in the Japanese food CRO industry, we are leading the research on the health state known as “**Suboptimal health**” (Japanese: 未病)



-  Individuals who are of suboptimal health might experience symptoms and/or have **borderline** lab values or measurements, but do not meet criteria for disease diagnosis.
-  As these individuals are not considered patients (i.e. not in a disease state), they are often recruited in clinical trials to evaluate the safety and efficacy of health products
-  From a prophylactic standpoint , this concept of suboptimal health helps people to **detect abnormalities of their body early** and **respond quickly**.

Suboptimal health and Borderline values

 Common examples of suboptimal health state and their corresponding borderline values:

Suboptimal Health State	Borderline Values
Borderline Hypertension	DBP: 80 – 89 mmHg and/or SBP: 130 – 139 mmHg
Pre-diabetes	75g Oral Glucose Tolerance Test: Cmax (t=2hr): 140 – 199 mg/dL
Overweight	BMI: 23 – 29 kg/m ²
Osteopenia	YAM score: 70 – 80% or T score: -1 – -2.5 SD
Hyperuricemia	Serum Uric Acid Level: 7.1 – 7.9 mg/dL
“Borderline” High LDL Cholesterol	LDL Cholesterol: 120 – 139 mg/dL
“Borderline” High Triglyceride	Triglyceride Cmax (t=2hr): 120 – 199 mg/dL
Liver Function that needs caution (Mildly elevated liver enzymes)	ALT: 31 – 50 (U/L) AST: 31– 50 (U/L)

Getting hold of suboptimal health state individuals is key to conducting a convincing clinical trial.



Participant Recruitment



Goトーロク

In ORTHOMEDICO Inc., a self-run website known as “**GO106.jp**” is used to recruit participants for clinical studies.

By providing free physical checkup to those registered to our database , we are able to constantly update it and hence have a full picture of the over **50,000** individuals registered in our system.



This has enabled us to gather the most eligible and representable individuals for each respective study of our client, enhancing the evaluation of safety and efficacy of food products, and improve the quality of studies.

Filtering and recruiting suboptimal health state individuals from our database is our strength.

General flow of the recruitment process

To join a study/ trial:



Free Registration

Decide type of study



Briefing session

Baseline Assessment

Start of Trial






Thumbnail examples of our recruitment advertisement

**肌の弾力が
気になる方**
(微細藻類含有サプリメント)

謝礼 **15,000 円**
募集人数: **180** 名

対 象 者: 健常な日本人成人男女の方
試験期間: 6週間
検査場所: 五反田駅 (品川区) 近くのクリニック
検査回数: 3回



To those that are particular
about the elasticity their skin

**夜間頻尿で
困っている方**
(ボタンボウフウ含有サプリメント)

謝礼 **24,000 円**
募集人数: **300** 名

対 象 者: 50歳以上の日本人男女の方
試験期間: 8週間
検査場所: 五反田駅 (品川区) 近くのクリニック
検査回数: 2回 (検査前事前説明会あり)



To those who are
troubled by nocturia

**歩行能力が落ちてきた
と感じている方**
(核酸含有サプリメント)

謝礼 **24,000 円**
募集人数: **50** 名

対 象 者: 40歳以上の健常な日本人男女の方
試験期間: 12週間
検査場所: 五反田駅 (品川区) 近くのクリニック
検査回数: 2回 (検査前事前説明会あり)



To those who are experiencing
weakness in walking



Recruitment via Social Media

- Approaching the general public and maximizing exposure with the help of common social media applications

Click the icons to see
our recruitment sites !





Market Research



Want to know more about Japanese market?

You can rely on us altogether from recruiting

volunteers, planning and managing product investigations, as well as result analysis.



Many individuals registered to our participant recruitment website GO106.jp are **considerably health- and beauty-conscious**. Their appraisals and criticism helped our clients understand better about consumers' opinions and preferences.

Moreover, our expertise in data analysis can assist you in quantifying the results and thereby give you feedback on the market research conducted.





Methods of investigation

Investigations are performed using the following 6 main methods



Face-to-face
interview



Group
interview



Telephone
interview



Face-to-face
questionnaire



Mail
questionnaire



Web
questionnaire

Example of past investigations



Highlights from a product opinion session (Fragrance preference survey- Face-to-face questionnaire)

Examples of products we help evaluate

Products	Example investigation/ assessment
Food and Beverage	Evaluation of new food product/ beverage Investigation of gender/age group preferences
Cosmetics and Beauty device	Evaluation of use of new product Survey of brand recognition Assessment of product naming Evaluation of impression conveyed in advertisement
Health device and Sports equipment	Evaluation of gender-wise/ age group-wise use Investigation of occupation-wise actual product use
Clothing	Fitting evaluation of new product Evaluation of brand impression
Electrical Appliance	Evaluation of use by housewives Investigation of idea for new product development



Examples of Market Research services

Receptivity Investigation

Purpose	To investigate the lifestyle of men who have high uric acid levels upon medical checkup
Target	30 – 49 year-old male with uric acid level above or equal to 6 mg/dL and below 8 mg/dL
Design	10 questions 200 participants
Cost	1,000,000 yen ~

Concept Assessment

Purpose	To understand the kind of dietary related issues that bother overweight adult male and female
Target	Adult male and female with BMI above or equal to 23 kg/m ³ and below 30 kg/m ³
Design	30 questions 100 participants
Cost	500,000 yen ~



 Please feel free to contact us if you have any enquiry !

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International Support Division



RICHARD SUN KWONG, LAI

Bachelor of Pharmacy, The University of Hong Kong

Registered Pharmacist of HKSAR

Considerable clinical experience as a pharmacist



XUN, LIU

Bachelor of Science, Tianjin Medical University

Master of Medical Science, University of Tsukuba

Ph.D., The University of Tokyo



Looking forward to working with you!
Thank you very much!!

